

## Guideline update for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 12: Pedicle screw fixation as an adjunct to posterolateral fusion

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The utilization of pedicle screw fixation as an adjunct to posterolateral lumbar fusion (PLF) has become routine, but demonstration of a definitive benefit remains problematic. The medical evidence indicates that the addition of pedicle screw fixation to PLF increases fusion rates when assessed with dynamic radiographs. More recent evidence, since publication of the 2005 Lumbar Fusion Guidelines, suggests a stronger association between radiographic fusion and clinical outcome, although, even now, no clear correlation has been demonstrated. Although several reports suggest that clinical outcomes are improved with the addition of pedicle screw fixation, there are conflicting findings from similarly classified evidence. Furthermore, the largest contemporary, randomized, controlled study on this topic failed to demonstrate a significant clinical benefit with the use of pedicle screw fixation in patients undergoing PLF for chronic low-back pain. This absence of proof should not, however, be interpreted as proof of absence. Several limitations continue to compromise these investigations. For example, in the majority of studies the sample size is insufficient to detect small increments in clinical outcome that may be observed with pedicle screw fixation. Therefore, no definitive statement regarding the efficacy of pedicle screw fixation as a means to improve functional outcomes in patients undergoing PLF for chronic low-back pain can be made. There appears to be consistent evidence suggesting that pedicle screw fixation increases the costs and complication rate of PLF. High-risk patients, including (but not limited to) patients who smoke, patients who are undergoing revision surgery, or patients who suffer from medical conditions that may compromise fusion potential, may appreciate a greater benefit with supplemental pedicle screw fixation. It is recommended, therefore, that the use of pedicle screw fixation as a supplement to PLF be reserved for those patients in whom there is an increased risk of nonunion when treated with only PLF.

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**KEY WORDS** • lumbar spine • pedicle screw • posterolateral fusion • adjunct • practice guidelines

### Recommendations

There is no evidence that conflicts with the previous recommendations published in the original version of the “Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine.”

*Abbreviations used in this paper:* DPQ = Dallas Pain Questionnaire; JOA = Japanese Orthopaedic Association; PLF = posterolateral lumbar fusion; SF-36 = 36-Item Short Form Health Survey.

### Grade B

Pedicle screw fixation is recommended when posterolateral lumbar fusion (PLF) is used to manage low-back pain in patients at high risk for pseudarthrosis.

Routine use of pedicle screw fixation as an adjunct to PLF for patients with degenerative disc disease is an option. There is consistent evidence that the use of pedicle screws enhances the fusion rate; however, a positive correlation with respect to clinical outcome has not been consistently demonstrated.

## Rationale

Arthrodesis of the lumbar spine has become an accepted treatment option for spinal disorders manifesting with low-back pain. Although there is an ever-increasing collection of techniques to achieve a successful arthrodesis, the traditional PLF remains a commonly performed and successful surgical approach. The inclusion of internal fixation through pedicle screw stabilization has become a routine addition to PLF. Pedicle screw fixation as an adjunct to PLF is known to have advantages, including a higher fusion rate, and disadvantages, including higher cost and a higher rate of complications. The purpose of this update is to review the current medical literature and determine if the evidence supports or refutes the role for pedicle screws as an adjunct of PLF in the treatment of degenerative spinal disorders, such as low-grade degenerative spondylolisthesis, leading to low-back pain.

### Search Criteria

A computerized search of the National Library of Medicine database of the literature published from July 2003 to December 2011 was performed using the following search terms: (((“Lumbosacral Region”[MeSH] OR “Lumbar Vertebrae”[MeSH]) AND “Spinal Fusion”[MeSH]) OR “lumbar fusion”[All Fields] OR (“lumbar”[title] AND “fusion”[title])) AND (“low back pain”[MeSH] OR (“low”[AllFields] AND “back”[AllFields] AND “pain”[All Fields]) OR “low back pain”[All Fields]) AND (“Bone Screws”[MeSH] OR “pedicle screw\*”[All Fields] AND (“2003”[PDAT]: “3000”[PDAT]) AND “humans”[MeSH] AND English[lang])) AND (“humans”[MeSH] AND English[lang] AND (“aged”[MeSH] OR “aged, 80 and over”[MeSH])). The search was limited to clinical series reported in English-language journals dealing with adult patients who had fusion with instrumentation for degenerative lumbar disease and yielded 258 publications. Among the articles reviewed, references were included if they described a comparison of fusion techniques with or without instrumentation. These references are summarized in Table 1.

## Scientific Foundation

There is a wealth of literature demonstrating the positive impact of pedicle screw fixation on fusion rates in patients treated with PLF. Although a small number of papers report an improvement in functional outcomes with pedicle screw fixation, the quality of these data is low from an evidence-based medicine perspective.<sup>9,13</sup> The results of the articles reviewed indicates that pedicle screw fixation for degenerative spondylosis has little if any impact on functional outcome.<sup>5,6,9,11</sup> This conclusion served as the basis for the recommendations of the previous Lumbar Fusion Guidelines.<sup>10</sup> Since our original review there have been several well-designed studies that address the utility of pedicle screw fixation in the context of degenerative disc disease of the lumbar spine.

Korsgaard et al. performed a randomized prospective study evaluating the impact of pedicle screws with respect to clinical outcome in 130 patients undergoing treatment

of degenerative lumbar disease.<sup>8</sup> All patients underwent PLF and were randomly assigned to either a noninstrumented or instrumented cohort. Fusion status was assessed using the Christensen classification, which utilizes static anteroposterior and lateral radiographs.<sup>3</sup> Clinical outcomes were evaluated using the Dallas Pain Questionnaire (DPQ). There were no significant differences between the treatment cohorts with respect to baseline demographic characteristics. At 2 years after surgery, no significant difference was observed between the 2 groups with respect to fusion rate or clinical outcome. Bjarke Christensen et al. reevaluated this same group of patients 5 years after surgery and found no significant difference in functional outcome; however, the authors did observe a higher reoperation rate in the instrumented group (25% vs 14% in the noninstrumented group).<sup>2</sup> It should be recognized, however, that only 11% of the reoperations in the instrumented group were for complications associated with the hardware. A subgroup analysis demonstrated that patients with “primary degenerative instability” experienced a greater improvement on the DPQ with instrumentation as compared with the noninstrumented cohort.

Andersen et al. performed a prospective nonrandomized study evaluating the role of pedicle screw fixation in patients over 60 years of age undergoing a posterolateral fusion with fresh-frozen allograft for degenerative lumbar spondylosis.<sup>1</sup> Pedicle screw stabilization was performed at the discretion of the operating surgeon. The authors used allograft in an attempt to avoid the morbidity associated with harvesting iliac crest autograft. The indications for a fusion included preoperative or anticipated iatrogenic instability, as well as significant back pain before surgery. Clinical outcome was assessed with the DPQ. Fusion status was assessed with static plain radiographs. All outcome measures were improved with instrumentation compared with noninstrumented fusion. The fusion rate was higher in the instrumented group (81% vs 68%). It should be remembered that the study was not randomized and the mean age of the patients in the instrumented group was lower than the mean age of the patients in the noninstrumented group.

Several case series have also provided evidence regarding PLF for degenerative lumbar spondylosis.<sup>7</sup> Epstein investigated the outcome in 75 cases involving geriatric patients who underwent noninstrumented lumbar fusion with local autograft and a beta-tricalcium phosphate graft extender.<sup>4</sup> Clinical outcome was assessed with the 36-Item Short Form Health Survey (SF-36), and fusion was assessed with CT scans and flexion-extension radiographs. In this study, Epstein documented a fusion rate of 83% and an improvement in all aspects of the SF-36, with the exception of mental health, which remained unchanged.

Tsutsumimoto et al. performed a retrospective analysis of a series of 42 cases involving patients who underwent noninstrumented PLF for degenerative lumbar stenosis.<sup>12</sup> Fusion status was assessed with flexion-extension radiographs, and clinical outcome was measured with the Japanese Orthopaedic Association (JOA) scale. The fusion rate was 74%. At 5 years postsurgery there was a significant improvement in the JOA scores of the patients in whom fusion was achieved when compared with those who had

## Part 12: Pedicle screw fixation as an adjunct to PLF

**TABLE 1: Pedicle screw fixation as an adjunct to PLF: summary of evidence\***

| Authors & Year                  | Level of Evidence | Brief Description   | Comments   |
|---------------------------------|-------------------|---|--|
| Korsgaard et al., 2002          | II                | Prospective randomized study of 130 pts w/ degenerative lumbar spondylosis. Pts underwent PLF w/ or w/o PS fixation. Follow-up 2 yrs. DPQ used for outcome assessment. Lumbar lordosis & fusion determined by plain radiographs. There was no significant btwn-groups difference on DPQ. No correlation btwn lordosis & DPQ. Fusion rate similar w/ or w/o PS fixation.   | No power calculation. Static radiographs used for fusion analysis. Nonstandard, divergent method of sacral screw insertion.  |
| Andersen et al., 2009           | III               | Prospective cohort study of 94 pts older than 60 yrs of age who underwent PLF w/ allograft. No instrumentation was used in 51 cases; PS fixation was used in 43. Outcome was assessed using DPQ, LBPRS, & SF-36. Fusion was assessed using plain radiographs. Pts were followed for 2–7 yrs. Pts treated w/ PS fixation had superior outcome (mean follow-up 4.3 yrs).  | Downgraded to Level III because fusion was assessed w/ static radiographs & the follow-up rate was 76%.  |
| Jäger et al., 2003              | III               | Prospective cohort study of 33 pts. All underwent PLF; instrumentation was used in 17 cases. Indication for surgery defined only as degenerative instability. Fusion was assessed w/ standard radiographs. Flexion-extension or CT was used only if needed. ODI was used. No difference reported in fusion or clinical outcomes. Pt accrual required 11 yrs, creating potential for substantial bias.   | Limitations included small sample size & lack of validated standard for evaluating radiographic evidence of fusion. Downgraded to Level III evidence.                                    |
| Bjarke Christensen et al., 2002 | II                | Prospective randomized study of 129 pts w/ chronic low-back pain. Pts were treated w/ PLF w/ or w/o PS fixation & followed for 5 yrs (93% follow-up). DPQ & LBPRS were used. For the entire cohort there were no statistically significant differences in functional outcome or fusion rates. Fusion was assessed w/ static radiographs. Subgroup analysis demonstrated that pts w/ isthmic spondylolisthesis had improved outcomes w/ noninstrumented PLF while pts w/ primary degenerative instability had better outcomes w/ instrumented PLF. | Block randomization, w/ power analysis. Static radiographs used for fusion analysis. Unclear if a standardized surgical technique utilized. LBPRS was not administered prior to surgery. |
| Fischgrund et al., 1997         | II                | Prospective randomized study of 76 pts w/ spondylolisthesis & spinal stenosis. Pts were randomized to PLF w/ or w/o PS fixation. Fusion rate was higher in instrumented group (82% vs 45%), while outcome was superior in noninstrumented group (85% vs 76%).   | Small sample size & nonvalidated outcome & fusion measures. Follow-up 88% at 2 yrs.  |
| Fritzell et al., 2002           | II                | Prospective randomized study of 222 pts randomized to PLF, PLF + PS fixation, & PLF + PS + IBF. Follow-up 91% at 2 yrs. All groups improved equally on VAS & ODI. Complication rates were 6%, 16%, & 31%.   | No power calculation. Underpowered.  |
| Lorenz et al., 1991             | II                | Prospective randomized study of 68 pts w/ disabling back pain. Pts were randomized to PLF or PLF + PS fixation. Follow-up at mean 26 mos w/ flexion-extension radiographs & RTW. Fusion rate, pain score, & RTW superior w/ PS fixation.  | RTW & pain score. Lack of validated outcome measure.   |
| Zdeblick, 1993                  | II                | Prospective, randomized study of 124 pts: PLF, PLF + semi-rigid PS fixation, PLF + PS. Fusion determined w/ flexion-extension radiographs at 1 yr: 65%, 77%, 95%.   | Clinical outcome measure not validated.  |

\* DPQ = Dallas Pain Questionnaire; IBF = interbody fusion; LBPRS = Low Back Pain Rating Scale; ODI = Oswestry Disability Index; PLF = posterolateral lumbar fusion; PS = pedicle screw; pt = patient; RTW = return to work; SF-36 = 36-Item Short Form Health Survey; VAS = visual analog scale.

pseudarthrosis (3.5 vs 2.5). Regression analysis revealed that fusion status and comorbidity were the strongest predictors of the improvement demonstrated on the JOA scale.

### Summary

The role of pedicle screw stabilization as an adjunct to PLF for lumbar degenerative disease continues to be an area of intense investigation. In the years since the original guideline publication, new evidence has been generated, demonstrating that the improved fusion rate with the use of pedicle screws can lead to improved clinical outcomes (Level II) and that pseudarthrosis is associated with worse long-term clinical outcome (Level IV). An improved fusion rate with the application of pedicle

screw stabilization has been well established from previous published reports. Although the recent literature is more suggestive of a relationship between successful fusion and improved clinical outcomes, a direct clinical benefit for the use of pedicle screws still has not been conclusively established. We therefore recommend that pedicle screws be used routinely as an adjunct to PLF for low-back pain only in cases that pose an increased risk for pseudarthrosis. Those cases include, but are not limited to, those involving patients who smoke, present with kyphotic deformity, or suffer systemic diseases associated with poor bone healing. The use of pedicle screw fixation in other cases is associated with an increase in the fusion rate, but any association with improved outcome is less well defined.

### Key Issues for Future Investigation

There is convincing support in the literature for the beneficial impact of pedicle screw fixation on arthrodesis. There is also support for the beneficial impact of a successful arthrodesis on clinical outcome. Nonetheless, studies examining the impact of pedicle screw fixation on clinical outcome have been inconclusive. Further investigation should elucidate the cause of this apparent contradiction. Possible explanations include the complication profile of pedicle screw insertion and the multifactorial aspect of clinical outcomes in this challenging patient population.

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